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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,195	05/12/1999	ERIC THIBAULT	410.016	5847

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EXAMINER
RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
2175	

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/308,195	THIBAULT ET AL.	
	Examiner	Art Unit	
	Sam Rimell	2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-8 and 10-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-8, 10-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over MDS Health Group Limited, hereafter referred to as "MDS".

Claim 15: MDS discloses functional steps of sequential and conditional validation, as shown in the flow chart of FIG. 2 and FIG. 5. Any step in the flow chart in which a decision must be made (as indicated by a diamond shaped block in the flow chart) reads as a step of conditional validation. All the steps in the flow chart are sequential steps. Based on the data collected, a certification is issued at the last step (FIG. 10 illustrating release of results). Any anomalies detected are reported in the result release of FIG. 10.

MDS only differs from claim 1 in that it does not disclose re-injecting cells. However, Examiner takes Official Notice that it is well known in the art to perform dialysis treatment where blood cells are removed from the body and subsequently re-injected. It would have been obvious to one of ordinary skill in the art to modify MDS to be used in the well known environment of a dialysis treatment, where some of the blood cells removed from the body are sampled and tested, and the remaining untested cells are returned to the body. This is a conventional protocol used in dialysis treatment to test the effectiveness of the treatment.

Claim 16: See remarks for claim 15.

Claim 2: FIG. 3 illustrates the requirement for a password input.

Claim 3: FIG. 3 is the certification screen page.

Claim 4: FIG. 7i shows a coded identification field in the top left corner (field for barcode number).

Claim 5: The step of printing certain screen pages, particularly the results screen page (FIG. 10) is well within the scope of the MDS reference.

Claim 6: Each test culture constitutes a "kit". The transfer of the kits to the testing laboratory is monitored by attributing a bar code to each kit so that each kit can be recorded as existing in the laboratory (See top left corner of FIG. 7(a) where bar codes are recorded for each test culture.

Claim 7: Modifying the test kits of MDS to be cytapheresis pouches would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 8: FIGS. 2 and 5 illustrate the process for carrying out control tests.

Claim 10: Any task defined in FIGS 2 or 5 constitute a management task.

Claim 11: The laboratory information system of MDS is connected to a network of laboratory computers (FIG. 1).

Claim 12: A dialysis procedure is a form of cell therapy.

Claim 13: Using the cell testing system of MDS in association with gene therapy as opposed to dialysis would have been obvious to one of ordinary skill in the art as a choice of design.

Claim 14: Any usage of a system constitutes training on that system.

Remarks

Applicant's amendments have overcome all previous rejections under 35 USC 112.

Applicant's arguments regarding the MDS reference have been considered.

Applicant argues that the MDS reference does not disclose the method steps of sequential and conditional validation for each functional stage. Applicant also argues that MDS does not disclose functional stages that are "punctually or systematically followed" by a validation stage. These arguments are not well taken. Examiner finds in FIGS. 2 and 5 the presence of decision points, such as 215, 230, 240, 260 and 262 that read as sequential and conditional validation steps. These decision points are sequential because they are presented in a specific order. They are conditional in that they allow for yes/no responses and they are acts of validation since the process cannot proceed unless the action described in the decision block has been completed. With respect to the question of functional stages being "punctually or systematically followed" by a validation stage, the claims make no such requirement. As recited in claims 15 and 16, the "sequential and conditional validation" is actually part of the "functional stage" and not separate from it (see in particular, the second paragraph, first line of claim 15, and the second paragraph, first line of claim 16). Claims 15 and 16 draw no separation between the functional stage and the validation and stage and recite no sequence between the two. Claims 15 and 16 only call for a sequence of validation stages, not a sequence of a functional stage followed immediately thereafter by a separate validation stage. Furthermore, even if claims 15 –16 were amended to define such features, they would be clearly anticipated by MDS, which illustrates specific

functional steps (illustrated by rectangular blocks in the flow chart) followed by specific validation steps (illustrated by diamond shaped blocks in the flow chart).

Applicant also argues that the MDS system does not require the same level of requirement in reliability and security as the process and system of applicant's invention. Presumably, applicant is referring back to the presence of validation steps, which as discussed above, do in fact exist in the MDS reference.

Applicant further argues that the MDS system can only be used by a single operator. However, the claims make no requirements on the number of operators that are needed or not needed to practice the invention.

Applicant further argues that it would not have been obvious for one skilled in the art to reach from the MDS teachings to a process and system for quality management in therapeutic processes that require the highest level of security and reliability as achieved by implementing sequential and conditional validation stages. Examiner has not stated that the feature of sequential and conditional validation is obvious in view of the MDS reference. Examiner has stated that this feature is fully taught by the MDS reference. The only basis for obviousness raised dealt with the issue of whether it would have been obvious to reinject treated cells to a patient.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
Art Unit 2166